

REMARKS

Claims 1, 6-9-21, and 26-27, and 29-30 are pending in the present Application. Claim 1 has been amended, Claims 22 and 25- 30 are canceled, leaving Claims 1 and 6-21 for consideration upon entry of the present amendment. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Amended Claims

Claim 1 is presently amended to better define the invention. Support for the amendment to Claim 1 can be found on page 11, paragraph [0034] of the specification as filed.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 6, 10 - 14 and 16 - 21 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent Application No. 2002/0177899 to Eum et al. (hereinafter “Eum”), in view of U.S. Patent No. 6,153,252 to Hossainy et al. (hereinafter “Hossainy”). (Office Action dated 11- 17 – 2008, page 2) Applicants respectfully traverse this rejection.

Claim 1 is directed to a medical device comprising: a nickel-titanium based shape memory alloy having a reverse martensitic transformation start (A_s) temperature of about 10°C to about 15°C and a transformation finish temperature (A_f) of about 30°C to about 35°C; and a drug coating comprising a polymeric resin and one or more biologically active agents; the polymeric resin being covalently bonded to the biologically active agents; the drug coating being disposed on the nickel-titanium based shape memory alloy.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, or knowledge generally available in the art at the time of the invention, must provide some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). “A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). To find obviousness, the Examiner must “identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*

Eum teaches a method of preparing Nitinol devices for insertion into the body. (see Col. 1, lines 1 – 3) Eum teaches that the stent is cooled to a temperature below the martensitic finish temperature (T_{mf}) prior to insertion into the delivery catheter. (see paragraph [0007]) Eum teaches that the stent is preferably manufactured from Nitinol and is fabricated with an Austenite start temperature (T_{as}) of 0 to 20°C, preferably in the range of 10°C or higher and an Austenite finish temperature (T_{af}) of 25 to 45°C, preferably $30 \pm 5^\circ\text{C}$. (see paragraph [0010]) Eum does not teach that the stent has disposed upon it a drug coating comprising a polymeric resin and one or more biologically active agents; the polymeric resin being covalently bonded to the biologically active agents. Eum further does not teach that the polymeric resin that is covalently bonded to the biologically active agents is a biodegradable polymer. Eum therefore does not teach all elements of the claimed invention.

Hossainy is directed to a process for coating stents comprising contacting the stent with a liquid coating solution containing a film forming biocompatible polymer under conditions suitable to allow the film forming biocompatible polymer to coat at least one surface of the stent. (Abstract) In discussing the film-forming polymers that may be used for coating, Hossainy discloses that “the polymers molecular weight [is] high enough to provide sufficient toughness so that the polymers will not be rubbed off during handling or deployment of the stent and must not crack during expansion of the stent.” (Col. 5, lines. 43-47) Subsequently, the reference goes on to disclose the optimal melting point of the polymer, and that elastomers are the preferred types of polymers. Specifically, Hossainy discloses that “[e]lastomers present the advantage that they tend to adhere well to the metal stents and can withstand significant deformation without cracking”. (Col. 7, lines 5-57)

Hossainy teaches that the stent is coated with a biocompatible polymer that is mixed with one or more therapeutic agents. (Col. 8, lines 36 – 38) Hossainy teaches that the biocompatible polymer is mixed with the therapeutic agents to form a mixture. Hossainy does not teach that the stent has disposed upon it a drug coating comprising a polymeric resin and one or more biologically active agents where the polymeric resin is covalently bonded to the biologically active agents. While Hossainy teaches biodegradable polymers, it specifically does not teach that the biodegradable polymers are covalently bonded to the biologically active agents.

Thus, while Hossainy discloses film-forming polymeric coatings, the reference too does not disclose all elements of present Claim 1. Since Hossainy does not make up for the deficiency

of Eum, Applicants contend there would be no motivation to combine the references.

Since neither Eum nor Hossainy teach all elements of the claimed invention, the Applicants believe that the Examiner has not made a prima facie case of obviousness over Eum in view of Hossainy. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claims 7 and 9 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum and Hossainy as applied to Claim 1 above and further in view of U.S. Patent No. 4,770,725 to Simpson et al. (hereinafter "Simpson") (Office Action dated 11-17-2008, page 5) Applicants respectfully traverse this rejection.

Claims 7 and 9 depend from Claim 1. Applicants respectfully submit that the combination proposed by the Examiner does not teach that the stent has disposed upon it a drug coating comprising a polymeric resin and one or more biologically active agents where the polymeric resin is covalently bonded to the biologically active agents.

As noted above, neither Eum nor Hossainy teach a drug coating comprising a polymeric resin and one or more biologically active agents where the polymeric resin is covalently bonded to the biologically active agents.

Simpson is directed to nickel-titanium-niobium alloys that have 2.5 to 30 wt% niobium and show a widening of the transformation hysteresis. (see Description of the Invention) The compositions disclosed by Simpson do not have a drug coating comprising a polymeric resin and one or more biologically active agents where the polymeric resin is covalently bonded to the biologically active agents.

For this reason at least, Simpson does not make up for the deficiency of Eum or Hossainy, and the combination of Eum and Hossainy in view of Simpson does not teach all elements of Claim 1. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claim 8 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum and Hossainy as applied to Claim 1 above and further in view of U.S. Patent No. 6,911,041 to Zscheeg. (hereinafter "Zscheeg") (Office Action dated 11-17-2008, page 5) Applicants respectfully traverse this rejection.

Claim 8 depends from Claim 1. As noted above, neither Eum nor Hossainy teach a drug coating comprising a polymeric resin and one or more biologically active agents where the polymeric resin is covalently bonded to the biologically active agents.

Zscheeg teaches an expandable stent for insertion into the body lumen. (see Abstract) Zscheeg teaches that the stent comprises 54.5 to 57 wt% nickel and 43 to 45.5 wt% titanium. (see Col. 7, lines 48 – 52) Zscheeg however does not teach a drug coating comprising a polymeric resin and one or more biologically active agents where the polymeric resin is covalently bonded to the biologically active agents. More specifically, Zscheeg does not teach that the polymeric resin is a biodegradable polymer that is covalently bonded to the biologically active agents. For this reason at least, Zscheeg does not teach all elements of the claimed invention. The combination of Eum with Hossainy and further in view of Zscheeg therefore does not teach all elements of the claimed combination. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claims 1 and 15 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of U.S. Patent No. 6,517,858 to Le Moel et al. (hereinafter “LeMoel”). (Office Action dated 11-17-2008, page 6) Applicants respectfully traverse this rejection.

As discussed previously, Eum does not disclose all elements of present Claim 1. Specifically, Eum does not disclose or suggest a nickel-based shape memory alloy having a reverse martensitic transformation start temperature of about 10°C to about 15°C.

LeMoel is directed to a bioactive implant comprising a substrate coated with a polymer layer with reactive functions, and a bioactive substance fixed on the implant by means of said reactive functions. (Abstract) The reference discloses the fixation of a heparin compound onto the polymer layer during the radiografting of the polymer precursor by adding the heparin to the grafting medium containing the precursor monomer to be grafted. (Col. 5, lines 52-57) LeMoel discloses that the substrate of the implant may be a metal or a metallic alloy. (Col. 2, lines 33-36) However, LeMoel does not disclose all elements of Claim 1.

While LeMoel discloses a metallic implant coated with a polymeric resin and a biological agent, LeMoel does not disclose or suggest that the polymeric resin is a biodegradable polymer that is covalently bonded to the biologically active agent as required by present Claim 1. LeMoel does not teach or suggest the use of biodegradable polymers or bioabsorbable polymers (as

termed in Hossainy). None of the polymers listed by LeMoel in Col. 3, lines 4 – 19 qualify as biodegradable polymers.

For at least this reason, the combination of Eum and LeMoel does not teach or suggest every element of the present claims. Further, since LeMoel does not make up for the deficiency of Eum, Applicants contend there would be no motivation to combine the references.

Applicants therefore believe that the Examiner has not made a *prima facie* case of obviousness over Eum in view of LeMoel. Applicants respectfully request a withdrawal for the obviousness rejection and an allowance of the claims.

Claim 26 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of U.S. Patent No. 6,911,041 to Zscheeg. (hereinafter “Zscheeg”) (Office Action dated 11-17-2008, page 7)

Claim 27 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum and Zscheeg as applied to Claim 26 above, and further in view of Hossainy (Office Action dated 11-17-2008, page 7)

Claim 29 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of Simpson (Office Action dated 11-17-2008, page 8)

Claim 30 stands rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Eum in view of Simpson and further in view of Hossainy (Office Action dated 11-17-2008, page 8) Applicants respectfully traverse this rejection.

Claims 26 – 30 have been canceled rendering these rejections moot.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the objection(s) and rejection(s) and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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